

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: EDMUND PFLEGER
GROSSMAN, TUCKER, PERREAULT &
PFLEGER, PLLC
55 SO. COMMERCIAL ST.
MANCHESTER, NH 03101

PCT **R** **E** **C** **E** **I** **V** **E** **D**
JUN 21 2010

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference ART053PCT	Date of mailing (day/month/year) FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/US2010/031602	International filing date (day/month/year) 19 April 2010
Applicant ARTHROSURFACE INCORPORATED	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 82 70

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver Telephone No. 571-272-7774
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PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: EDMUND PFLEGER
GROSSMAN, TUCKER, PERREAULT &
PFLEGER, PLLC
55 SO. COMMERCIAL ST.
MANCHESTER, NH 03101

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NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing
(day/month/year)

18 JUN 2010

Applicant's or agent's file reference

ART053PCT

FOR FURTHER ACTION See paragraphs 1 and 4 below

International application No.

PCT/US2010/031602

International filing date

(day/month/year)

19 April 2010

Applicant

ARTHROSURFACE INCORPORATED

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 82 70

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest against payment of (an) additional fee(s) under Rule 40.2,** the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

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The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Authorized officer:

Blaine R. Copenheaver

Telephone No. 571-272-7774

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference ART053PCT	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US2010/031602	International filing date <i>(day/month/year)</i> 19 April 2010	(Earliest) Priority Date <i>(day/month/year)</i> 17 April 2009
Applicant ARTHROSURFACE INCORPORATED		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed
☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II)

3. ☐ **Unity of invention is lacking** (see Box No. III)

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant
☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☒ the text is approved as submitted by the applicant
☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 1
☒ as suggested by the applicant
☐ as selected by this Authority, because the applicant failed to suggest a figure
☐ as selected by this Authority, because this figure better characterizes the invention
b. ☐ none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2010/031602

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/56 (2010.01)

USPC - 606/79

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61B 17/56 (2010.01)

USPC - 606/79, 81, 86R, 88, 89, 96, 99, 102, 304

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Patbase, Google Scholar

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2006/0190002 A1 (TALLARIDA et al) 24 August 2006 (24.08.2006) entire document	1-20
Y	US 2005/0043805 A1 (CHUDIK) 24 February 2005 (24.02.2005) entire document	1-20
A	US 2006/0058883 A1 (ARAM et al) 16 March 2006 (16.03.2006) entire document	1-20
A	US 2007/0179608 A1 (EK et al) 02 August 2007 (02.08.2007) entire document	1-20

☐ Further documents are listed in the continuation of Box C.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier application or patent but published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

01 June 2010

Date of mailing of the international search report

18 JUN 2010

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Authorized officer:

Blaine R. Copenheaver

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: EDMUND PFLEGER
GROSSMAN, TUCKER, PERREAULT &
PFLEGER, PLLC
55 SO. COMMERCIAL ST.
MANCHESTER, NH 03101

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) **18 JUN 2010**

Applicant's or agent's file reference
ART053PCT

FOR FURTHER ACTION

See paragraph 2 below

International application No.
PCT/US2010/031602

International filing date (day/month/year)
19 April 2010

Priority date (day/month/year)
17 April 2009

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61B 17/56 (2010.01)
USPC - 606/79

Applicant ARTHROSURFACE INCORPORATED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Date of completion of this opinion

01 June 2010

Authorized officer:

Blaine Copenheaver

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2010/031602

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:
 - a. type of material
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed
 - ☐ filed together with the international application in electronic form
 - ☐ furnished subsequently to this Authority for the purposes of search
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2010/031602

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-20	YES
	Claims	None	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-20	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-20 lack an inventive step under PCT Article 33(3) as being obvious over Tallarida et al. (hereinafter Tallarida) in view of Chudik.

Regarding claim 1, Tallarida discloses a method for repairing a defect on a portion of an articular surface (Abstract and Para. [0098] Fig. 1 shows a surgically implanted articular joint surface repair system), said method comprising: securing a guide pin to said articular surface of said glenoid proximate to said defect (Para. [0019] once the defect of the chondral surface has been identified, a guide pin is inserted arthroscopically), wherein said guide pin defines a working axis and said working axis is positioned at an angle A relative to the articular surface (Para. [0108] shaft 111 can be angularly repositioned so that it becomes more coaxial to the reference axis 20A; when compass 120 is in its proper position at or near the implant target site, the guide pin 20 is delivered through the instrument cannulation 113, re-establishing the working axis 20A used to define the implant geometry), wherein angle A is less than or equal to 90 degrees (Para. [0128] ...accomplished by adjusting the angle A (Fig. 19a) of the bone-contacting surface 42 of the implant 40 and a corresponding angle of the preparation tool); advancing an excision device over said guide pin (Para. [0110] As illustrated in Fig. 16, when fitted with a cutting blade 121, and with the guide pin 20 advanced through the shaft 113 of instrument 120, so that the guide pin passes through a closely sized hole 116 in the cutting blade, the blade's position becomes fully constrained), wherein said excision device includes a cannulated shaft (Para. [0108] In the embodiment shown in Fig. 15a, compass instrument 120 includes handle 110, a cannulated shaft 111 that extends through the handle, and a cannulated distal offset arm 112...) and at least one cutter extending radially outwardly from said cannulated shaft, wherein said at least one cutter is generally aligned in a single plane extending along a longitudinal axis of said cannulated shaft (Para. [0110] As illustrated in Fig. 16, when fitted with a cutting blade 121, and with the guide pin 20 advanced through the shaft 113 of instrument 120, so that the guide pin passes through a closely sized hole 116 in the cutting blade, the blade's position becomes fully constrained), but fails to explicitly disclose the method wherein the articular surface is of a patient's glenoid and rotating said excision device about said guide pin to form a generally hemispherical excision site within the articular surface of the glenoid around said guide pin. However Chudik teaches a method for shoulder replacement surgery (Chudik Abstract) wherein the articular surface is of a patient's glenoid (Chudik Para. [0020] aspect of the present invention regards a transhumeral glenoid reamer with a working head and a removably attached transhumeral shaft) and rotating said excision device about said guide pin to form a generally hemispherical excision site within the articular surface of the glenoid around said guide pin (Chudik Para. [0117] For a novel humeral implant 94, a hemispherically shaped reaming surface 37, sized similarly to a novel humeral surface 96 implant component is used, having similar depth and radius of curvature (FIG. 7c)). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Tallarida to include repair of a defect at a patient's glenoid wherein a cutter forms a hemispherical excision site as taught by Chudik for the purpose of insuring an optimal fit at the site of an articular surface repair within a patient.

Regarding claim 2, Tallarida in view of Chudik discloses the method of claim 1. Tallarida further discloses the method wherein said guide pin is configured to be disposed at an angle A relative to the articular surface, wherein $90 \text{ degrees} > A > 45 \text{ degrees}$ (Para. [0128] adjusting the angle A (Fig. 19a) of the bone-contacting surface 42 of the implant 40 and a corresponding angle of the preparation tool. This also allows for a correction of the implant geometry, to compensate for any non-perpendicular placement of the guide pin with respect to the articular surface). Further, it would have been obvious to one of ordinary skill in the art at the time of the invention to dispose the guide pin at a desired angle relative to a plane in an articular surface repair, since where the general conditions of a claim are disclosed in the prior art, discovering the optimum range of a result effective variable involves only routine skill in the art and for the purpose of insuring an optimal fit at the site of an articular surface repair within a patient.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2010/031602

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Regarding claim 3, Tallarida in view of Chudik discloses the method of claim 1. Tallarida discloses the method further comprising removing said guide pin and placing an implant in said excision site (Para. [0048] Fig. 8b is a sagittal view of the exemplary fixation screw and hex-shaped proximal extension of FIG. 8a implanted in the defect after removal of an exemplary socket type driver and guide pin).

Regarding claim 4, Tallarida in view of Chudik discloses the method of claim 1. Tallarida further discloses the method wherein said defect is disposed proximate to a perimeter of said articular surface and wherein said excision site extends to said perimeter (Para. [0019] once the defect of the chondral surface has been identified, a guide pin is inserted arthroscopically; Figs. 8A, 11A, and 11B)).

Regarding claim 5, Tallarida in view of Chudik discloses the method of claim 4. Tallarida further discloses the method wherein said defect comprises a missing portion of said perimeter of said articular surface (Para. [0098] As an overview, Fig. 1 shows a surgically implanted articular joint surface repair system consistent with the present invention. As shown, the assembled fixation device includes fixation screw 10, implant 40, and anchoring pin 5, implanted in the defect in the medial femoral chondral surface 55 of knee 50. Implant 40 is configured so that bearing or bottom surface 41 of the implant reproduces the anatomic contours of the surrounding articular surface of the knee 50).

Regarding claim 6, Tallarida in view of Chudik discloses the method of claim 1. Tallarida further discloses the method wherein said at least one cutter includes a first cutter and a second cutter (Para. [0026] ... a cannulated distal offset arm configured to serve as a linearly adjustable mounting tool for a series of cutting blades, boring blades, or measuring probes), which extend generally radially outwardly from the cannulated shaft at an angle of approximately 180 degrees from each other (see cutting blade 121 at Fig. 16; Paras. [0109] and [0110]).

Regarding claim 7, Tallarida in view of Chudik discloses the method of claim 1. Tallarida fails to explicitly disclose the method wherein said at least one cutter has a cross-sectional thickness of 0.5 mm to 3.0 mm. It would have been obvious to one of ordinary skill in the art at the time of the invention to include a thickness in the range of 0.5 mm to 3.0 mm, since where the general conditions of a claim are disclosed in the prior art, discovering the optimum range of a result effective variable involves only routine skill in the art and for the purpose of insuring an optimal fit at the site of an articular surface repair within a patient.

Regarding claim 8, Tallarida discloses a method for repairing a defect on a portion of an articular surface (Abstract and Para. [0098] Fig. 1 shows a surgically implanted articular joint surface repair system), said method comprising: securing a guide pin to said articular surface of said glenoid proximate to said defect (Para. [0019] once the defect of the chondral surface has been identified, a guide pin is inserted arthroscopically), wherein said guide pin defines a working axis and said working axis is positioned at an angle A relative to the articular surface (Para. [0108] shaft 111 can be angularly repositioned so that it becomes more coaxial to the reference axis 20A; when compass 120 is in its proper position at or near the implant target site, the guide pin 20 is delivered through the instrument cannulation 113, re-establishing the working axis 20A used to define the implant geometry), and advancing an excision device over said guide pin (Para. [0110]), wherein said excision device includes a cannulated shaft and at least one cutter extending radially outwardly from said cannulated shaft (Paras. [0108] through [0110]), wherein said at least one cutter is generally aligned in a single plane extending along a longitudinal axis of said cannulated shaft (Para. [0110]), but fails to explicitly disclose the method for an articular surface of a patient's glenoid wherein angle A is selected to avoid contact with a corresponding humerus and rotating said excision device about said guide pin to form a generally hemispherical excision site within the articular surface of the glenoid around said guide pin. However Chudik teaches a method for shoulder replacement surgery (Chudik Abstract) wherein the articular surface is of a patient's glenoid (Chudik Para. [0020] aspect of the present invention regards a transhumeral glenoid reamer with a working head and a removably attached transhumeral shaft) wherein angle A is selected to avoid contact with a corresponding humerus (Chudik Para. [0116] the transhumeral protective sheath 38 of the present invention provides protection for the bone within which the transhumeral portal sits) and rotating said excision device about said guide pin to form a generally hemispherical excision site within the articular surface of the glenoid around said guide pin (Chudik Para. [0117] For a novel humeral implant 94, a hemispherically shaped reaming surface 37, sized similarly to a novel humeral surface 96 implant component is used, having similar depth and radius of curvature (Fig. 7c)). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Tallarida to include repair of a defect at a patient's glenoid to avoid contact with a patient's humerus wherein a cutter forms a hemispherical excision site as taught by Chudik for the purpose of insuring an optimal fit at the site of an articular surface repair within a patient and avoiding undesired damage to surrounding tissues in the area of resurfacing.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Regarding claim 9, Tallarida discloses a system for repairing a defect on a portion of an articular surface (Abstract and Para. [0098] Fig. 1 shows a surgically implanted articular joint surface repair system), said system comprising: a guide pin configured to be secured into bone beneath the articular surface of the glenoid (Para. [0019] once the defect of the chondral surface has been identified, a guide pin is inserted arthroscopically); an excision device (Para. [0110]) including: a cannulated shaft configured to be advanced over said guide pin (Para. [0108] ...in Fig. 15a, compass instrument 120 includes handle 110, a cannulated shaft 111 that extends through the handle, and a cannulated distal offset arm 112...), and at least one cutter (Para. [0110]); and an implant including a load bearing surface and a bone facing surface (Para. [0022] define a three dimensional surface matched to the bearing surface geometry to be implanted and reproduce the anatomic contours mapped; Para. [0023]), wherein said load bearing surface exhibits a contour substantially corresponding to the contour of the articular surface (Paras. [0022] and [0023]), but fails to explicitly disclose the system at an articular surface of a patient's glenoid and the cutter configured to form a generally hemispherical excision site in said glenoid about said guide pin and wherein said at least one cutter has a cross-sectional thickness of 0.5 mm to 3.0 mm and said at least one cutter includes a cutting surface having a generally arcuate shape sweeping towards a proximal end of said cannulated shaft and said generally hemi-spherical bone facing surface is configured to be received in said generally hemispherical excision site. However Chudik teaches a system for shoulder replacement surgery (Chudik Abstract) wherein the articular surface is of a patient's glenoid (Chudik Para. [0020] aspect of the present invention regards a transhumeral glenoid reamer with a working head and a removably attached transhumeral shaft) and the cutter configured to form a generally hemispherical excision site in said glenoid about said guide pin and said generally hemi-spherical bone facing surface is configured to be received in said generally hemispherical excision site (Chudik Para. [0117] For a novel humeral implant 94, a hemispherically shaped reaming surface 37, sized similarly to a novel humeral surface 96 implant component is used, having similar depth and radius of curvature (Fig. 7c)). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Tallarida to include repair of a defect at a patient's glenoid to avoid contact with a patient's humerus wherein a cutter forms a hemispherical excision site as taught by Chudik for the purpose of insuring an optimal fit at the site of an articular surface repair within a patient and avoiding undesired damage to surrounding tissues in the area of resurfacing. Further, it would have been obvious to one of ordinary skill in the art at the time of the invention to include a thickness in the range of 0.5 mm to 3.0 mm, since where the general conditions of a claim are disclosed in the prior art, discovering the optimum range of a result effective variable involves only routine skill in the art and for the purpose of insuring an optimal fit at the site of an articular surface repair within a patient. In addition, it would have been obvious to one of ordinary skill in the art at the time of the invention to include a cutting surface having a generally arcuate shape, since a mere change in the shape of a device involves only routine skill in the art and for the purpose of insuring an optimal fit at the site of an articular surface repair within a patient.

Regarding claim 10, Tallarida in view of Chudik discloses the system of claim 9. Tallarida further discloses the system wherein said guide pin is configured to be disposed at an angle A relative to the articular surface, wherein angle A is < 90 degrees (Para. [0128] adjusting the angle A (Fig. 19a) of the bone-contacting surface 42 of the implant 40 and a corresponding angle of the preparation tool. This also allows for a correction of the implant geometry, to compensate for any non-perpendicular placement of the guide pin with respect to the articular surface). Further, it would have been obvious to one of ordinary skill in the art at the time of the invention to dispose the guide pin at a desired angle relative to a plane in an articular surface repair, since where the general conditions of a claim are disclosed in the prior art, discovering the optimum range of a result effective variable involves only routine skill in the art and for the purpose of insuring an optimal fit at the site of an articular surface repair within a patient.

Regarding claim 11, Tallarida in view of Chudik discloses the system of claim 9. Tallarida further discloses the system wherein said guide pin is configured to be disposed at an angle A relative to said articular surface, wherein $90 \text{ degrees} \geq A \geq 45 \text{ degrees}$ (Para. [0128] ... accomplished by adjusting the angle A (Fig. 19a) of the bone-contacting surface 42 of the implant 40 and a corresponding angle of the preparation tool).

Regarding claim 12, Tallarida in view of Chudik discloses the system of claim 9. Tallarida further discloses the system wherein said at least one cutter includes a first cutter and a second cutter (Para. [0026] ... a cannulated distal offset arm configured to serve as a linearly adjustable mounting tool for a series of cutting blades, boring blades, or measuring probes), wherein said first and second cutters extend generally radially outwardly from said cannulated shaft at an angle approximately 180 degrees from each other (see cutting blade 121 at Fig. 16; Paras. [0109] and [0110]). Further, it would have been obvious to one of ordinary skill in the art at the time of the invention to position the cutting blades 180 degrees opposite each other, since a mere rearrangement of parts of a device involves only routine skill in the art and for the purpose of providing dynamic balance to the device and thereby facilitate stability.

Regarding claim 13, Tallarida in view of Chudik discloses the system of claim 9. Tallarida further discloses the system wherein an overall radius R, of said at least one cutter defines a radius of said excision site created by said excision device (Para. [0027] With the guide pin advanced through the instrument shaft, when fitted with a blade, a fixed length from the rotational or reference axis to the cutting blade's cutting surface is established. This defines the radius that is effected as the instrument is rotated around the guide pin, and corresponds to the overall diameter of the implant. This sharp cutting blade is used to circumscribe and cleanly cut the surrounding articular cartilage).

Regarding claim 14, Tallarida in view of Chudik discloses the system of claim 13. Tallarida further discloses the system wherein said overall radius R, substantially corresponds to a radius R, of said implant (Para. [0027]).

Regarding claim 15, Tallarida in view of Chudik discloses the system of claim 9. Tallarida further discloses the system wherein said impact guide includes an impact guide arm and said impact device includes a proximal end and a distal end (Para. [0110] cutting blade 121), and said proximal end of said impact device is configured to be disposed generally parallel to said impact guide arm when said distal end is received in said impact slot (Paras. [0108] and [0110]).

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2010/031602

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Regarding claim 16, Tallarida in view of Chudik discloses the system of claim 9 [as best understood]. Tallarida further discloses the system wherein said depth D substantially corresponds to a height H of said implant (Para. [0106]).

Regarding claim 17, Tallarida in view of Chudik discloses the system of claim 9. Tallarida further discloses the system wherein said load bearing surface comprises a beveled region disposed about a perimeter of said load bearing surface (Fig. 19d at notch 386; Paras. [0127], [0142], and [0143]).

Regarding claim 18, Tallarida in view of Chudik discloses the system of claim 9. Tallarida further discloses the system wherein said bone facing surface comprises at least one lip, protrusion and/or rib configured to increase a mechanical connection between said implant and bone within said excision site (Paras. [0142] and [0143]; Para. [0127] As shown in Fig. 19b, outer diameter 190 may include a slight outward taper or protrusion 197 along the diametrical surface to enhance load bearing or load transfer properties of the implant to surrounding bone).

Regarding claim 19, Tallarida in view of Chudik discloses the system of claim 9. Tallarida further discloses the system wherein said implant comprises at least one keel extending generally outwardly from said bone facing surface (Para. [0127] As shown in Fig. 19b, outer diameter 190 may include a slight outward taper or protrusion 197 along the diametrical surface to enhance load bearing or load transfer properties of the implant to surrounding bone).

Regarding claim 20, Tallarida in view of Chudik discloses the system of claim 19. Tallarida further discloses the system wherein said at least one keel includes a protrusion disposed about a distal end of a base region (Para. [0127] and Fig. 19b).

Claims 1-20 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Annex B).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, International Phase, paragraph 296).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet or sheets containing a complete set of claims in replacement of all the claims previously filed must be submitted.

Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively in Arabic numerals (Section 205(a)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

SEQUENCE LISTINGS AND TABLES RELATED THERETO IN INTERNATIONAL APPLICATIONS FILED IN THE U.S. RECEIVING OFFICE

The Administrative Instructions (AIs) under the Patent Cooperation Treaty (PCT), in force as of **July 1, 2009**, contain important changes relating to the manner of filing, and applicable fees for, sequence listings and/or tables related thereto (sequence-related tables) in international applications. The complete text may be accessed at <http://www.wipo.int/pct/en/texts/index.htm>.

Effective July 1, 2009, Part 8 and Annex C-*bis* will no longer form part of the AIs. Part 8 was introduced in 2001 as a temporary solution to problems arising from the filing of very large sequence listings on paper and provided for a *sequence listing forming part of the international application* to be filed in electronic form on physical medium (e.g., CD), together with the remainder of the application on paper. In 2002, Part 8 was expanded to include sequence-related tables and Annex C-*bis* was added to provide technical requirements. All applicants may now file complete international applications in electronic form, eliminating the need for these temporary provisions.

I. AIs PART 8 AND ANNEX C-BIS DELETED AS OF JULY 1, 2009

- A) **Sequence-related tables cannot be filed as a separate part of the description or in text format.** They must be provided as an integral part of the international application either:
- in PDF format as part of an international application filed in electronic form via EFS-Web; or
 - on paper as part of an international application filed on paper.
- B) **A *sequence listing forming part of an international application* may be provided either:**
- in electronic form, as part of an international application filed in electronic form via EFS-Web, in
 - Annex C/ST.25 text format (preferred), or
 - PDF format; or
 - on paper as part of an international application filed on paper.
- C) **A *sequence listing not forming part of the international application* (for search under PCT Rule 13ter) in Annex C/ST.25 text format**
- is not required where the *sequence listing forming part of the international application* was filed in Annex C/ST.25 text format as part of an international application filed in electronic form via EFS-Web
 - is required for search where the *sequence listing forming part of the international application* was filed in PDF
 - is required for search on physical medium (e.g., CD) where the *sequence listing forming part of the international application* was filed on paper as part of an international application filed on paper.

II. CALCULATION OF THE INTERNATIONAL FILING FEE AND FEE REDUCTION UNDER AI § 707

- A) **A sequence-related table** must form an integral part of the international application and will incur FULL page fees with no upper limit.
- B) **A *sequence listing forming part of an international application* filed:**
- via EFS-Web in Annex C/ST.25 text format will incur NO page fees;
 - on paper or in PDF format will incur FULL page fees with no upper limit.

III. AVAILABILITY OF SEQUENCE LISTINGS SUBMITTED FOR SEARCH UNDER PCT RULE 13TER

International Searching Authorities will be required to transmit to the International Bureau a copy of an Annex C/ST.25 text format sequence listing provided for search under PCT Rule 13ter. Any such sequence listing will be made available on PATENTSCOPE® (*sequence listings forming part of the international application* are already available).

IV. JULY 2009 REQUEST (PCT/RO/101)

The Request now has two options for the last sheet: one for paper filings; and one for EFS-Web filings. The July 2009 Request may be accessed at <http://www.wipo.int/pct/en/forms/index.htm>.